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13	Bard Peripheral Vascular, Inc.										
14											
15	IN THE UNITED STA	ATES DISTRICT COURT									
16	FOR THE DIST	RICT OF ARIZONA									
17	TOR THE DIST	RICT OF ARIZONA									
18	IN RE: Bard IVC Filters Products Liability Litigation	MDL NO. 15-02641-PHX-DGC									
19	This Document Relates to:										
20	PATRICIA JONES,	-									
21	Plaintiff,	Case No. CV-15-02647-PHX-DGC									
2223	v.	DEFENDANTS C. R. BARD, INC. AND									
23 24	C. R. BARD, INC., a foreign corporation, AND BARD PERIPHERAL VASCULAR	BARD PERIPHERAL VASCULAR, INC.'S ANSWER AND AFFIRMATIVE									
25	INC., an Arizona corporation,	DEFENSES AND DEMAND FOR TRIAL BY JURY									
26	Defendants.	_									
27											
28	II										

Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV") (Bard and BPV are collectively "Defendants") answer the Complaint ("Plaintiff's Complaint") of Plaintiff Patricia Jones ("Plaintiff") as follows:

INTRODUCTORY ALLEGATIONS

- 1.1 Defendants admit that Plaintiff has brought this civil action for damages but deny that Plaintiff has suffered any personal injuries caused by Defendants, deny that Defendants are liable to Plaintiff, and deny that Plaintiff is entitled to any damages from Defendants. Defendants deny any remaining allegations contained in Paragraph 1 of Plaintiff's Complaint.
- 2. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters under the trademarks G2®, G2®X, G2® Express, EclipseTM, MeridianTM, and DenaliTM Filter Systems. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademarks G2®, G2®X, G2® Express, EclipseTM, MeridianTM, and DenaliTM Filter Systems. The allegations contained in Paragraph 3 of Plaintiff's Complaint referencing the Recovery® Cone contain no factual allegations directed at Defendants and, therefore, require no response. To the extent a response is required, those allegations are denied. Defendants deny any remaining allegations contained in Paragraph 2 of Plaintiff's Complaint.
- 3. Defendants admit that Plaintiff has brought this civil action for damages but deny that Plaintiff has suffered any personal injuries caused by Defendants, deny that Defendants are liable to Plaintiff, and deny that Plaintiff is entitled to any damages from Defendants. Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiff's Complaint.

Plaintiff's Complaint contains no numbered paragraphs. For the ease of the Court, Defendants will associate numbers with each paragraph as delineated by an indention.

- 4. Defendants deny the allegations contained in Paragraph 4 of Plaintiff's Complaint.
 5. Defendants deny the allegations contained in Paragraph 5 of Plaintiff's Complaint.
- 6. Defendants deny that any of its inferior vena cava filter products are unreasonably dangerous or defective in any manner. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants deny any remaining allegations contained in Paragraph 6 of Plaintiff's Complaint.
- 7. Defendants deny the allegations contained in Paragraph 7 of Plaintiff's Complaint.

PARTIES

- 8. Defendants admit that Plaintiff has brought this civil action for damages but deny that Plaintiff has suffered any personal injuries caused by Defendants, deny that Defendants are liable to Plaintiff, and deny that Plaintiff is entitled to any damages from Defendants. Defendants deny any remaining allegations contained in Paragraph 8 of Plaintiff's Complaint.
- 9. Defendants deny the allegations contained in Paragraph 9 of Plaintiff's Complaint.
- 10. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 10 of Plaintiff's Complaint regarding either Plaintiff's citizenship and/or residency or the trade name of any inferior vena cava filter implanted in Plaintiff and, therefore, deny them. Defendants deny any remaining allegations contained in Paragraph 10 of Plaintiff's Complaint.
- 11. Defendants deny the allegations contained in Paragraph 11 of Plaintiff's Complaint.

- 12. Defendants deny that Bard is a Delaware Corporation. Defendants admit that Bard is a New Jersey Corporation. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters under the trademarks Recovery®, G2®, G2®X, G2® Express, EclipseTM, MeridianTM, and DenaliTM Filter Systems. Defendants admit that Bard is authorized to do business, and does business, in the State of Arizona. Defendants deny any remaining allegations contained in Paragraph 12 of Plaintiff's Complaint.
 - 13. Defendants admit that BPV is an Arizona Corporation. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademarks Recovery®, G2®, G2®X, G2® Express, EclipseTM, MeridianTM, and DenaliTM Filter Systems. Defendants admit that BPV is authorized to do business, and does business, in the State of Arizona. Defendants deny any remaining allegations contained in Paragraph 13 of Plaintiff's Complaint.
 - 14. Defendants deny the allegations contained in Paragraph 14 of Plaintiff's Complaint.
 - 15. Defendants deny the allegations contained in Paragraph 15 of Plaintiff's Complaint.
 - 16. Defendants deny the allegations contained in Paragraph 16 of Plaintiff's Complaint.
 - 17. The allegations contained in Paragraph 17 of Plaintiff's Complaint are not directed at Defendants, requiring no response. To the extent a response is required, Defendants deny those allegations.
 - 18. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants deny any remaining allegations contained in Paragraph 18 of Plaintiff's Complaint.

- 19. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants also admit that inferior vena cava filters may also be used to treat patients who are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants deny any remaining allegations contained in Paragraph 19 of Plaintiff's Complaint.
 - 20. Defendants deny the allegations contained in Paragraph 20 of Plaintiff's Complaint.

JURISDICTION AND VENUE

- 21. Regarding Paragraph 21 of Plaintiff's Complaint, Defendants do not contest that the injuries and damages alleged within Plaintiff's Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been, and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Northern District of Georgia.
- 22. Regarding Paragraph 22 of Plaintiff's Complaint, Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Northern District of Georgia.
- 23. Defendants admit that the Judicial Panel of Multidistrict Litigation recently consolidated certain claims related to Bard IVC filters into MDL No. 2461, the venue for which is the United States District Court for the District of Arizona and over which Judge David Campbell presides. Defendants deny any remaining allegations contained in Paragraph 23 of Plaintiff's Complaint.

- 24. Defendants admit that the Judicial Panel of Multidistrict Litigation recently consolidated certain claims related to Bard IVC filters into MDL No. 2461, the venue for which is the United States District Court for the District of Arizona and over which Judge David Campbell presides. Defendants deny any remaining allegations contained in Paragraph 24 of Plaintiff's Complaint.
 - 25. The allegations contained in Paragraph 25 of Plaintiff's Complaint are conclusions of law, to which no response is required. To the extent a response is required, Defendants deny those allegations.

BACKGROUND

- 26. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market or the identity of manufacturers of inferior vena cava filters. Defendants deny any remaining allegations of Paragraph 26 of Plaintiff's Complaint.
- 27. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants further admit that inferior vena cava filters may be designed for permanent placement, temporary placement, or both. Defendants deny any remaining allegations of Paragraph 27 of Plaintiff's Complaint.
- 28. Defendants admit that the inferior vena cava is a large vein that receives blood from the lower regions of the body and delivers it to the right atrium of the heart. Defendants further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to human health, including sometimes death. Defendants deny any remaining allegations of Paragraph 28 of Plaintiff's Complaint.
- 29. Defendants admit that patients at a high risk for developing deep vein thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy, including but not limited to the medications listed in Paragraph 29 of Plaintiff's Complaint. Defendants further admit that inferior vena cava filters may also be used to treat patients who

- are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 29 of Plaintiff's Complaint and, on that basis, deny them.
- 30. Defendants lack knowledge or information or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market. Defendants also lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding doctors' use of permanent filters. Defendants deny any remaining allegations contained in Paragraph 30 of Plaintiff's Complaint.
- 31. Defendants deny the allegations contained in Paragraph 31 of Plaintiff's Complaint.
- 32. Defendants deny the allegations contained in Paragraph 32 of Plaintiff's Complaint.
- 33. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding the medical community's concerns regarding the desirability of a retrievable filter. Defendants deny any remaining allegations of Paragraph 33 of Plaintiffs' Complaint.
- 34. Defendants lack knowledge or information sufficient to admit or deny the allegations regarding the intent of any other manufacturers in developing inferior vena cava filter products. Defendants deny any remaining allegations of Paragraph 34 of Plaintiffs' Complaint.
- 35. Defendants admit that the Recovery® Filter was cleared by the FDA for retrievable placement on July 25, 2003, pursuant to applications submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 35 of Plaintiff's Complaint.
- 36. Defendants deny the allegations contained in Paragraph 36 of Plaintiff's Complaint.

1 37. Defendants deny the allegations contained in Paragraph 37 of Plaintiff's 2 Complaint. 3 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiff's 4 Complaint. 5 39. Defendants deny the allegations contained in Paragraph 39 of Plaintiff's 6 Complaint. 7 40. Defendants deny the allegations contained in Paragraph 40 of Plaintiff's 8 Complaint. 9 41. Defendants admit the G2® Filter System was cleared by the United States Food 10 and Drug Administration in 2005 for permanent use pursuant to an application submitted 11 under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny the remaining 12 allegations contained in Paragraph 41 of Plaintiff's Complaint. 13 42. Defendants admit that the FDA initially declined to clear the G2® Filter. 14 Defendants deny any remaining allegations contained in Paragraph 42 of Plaintiff's Complaint. 15 16 43. Defendants deny the remaining allegations contained in Paragraph 43 of 17 Plaintiff's Complaint. 18 44. Defendants deny the remaining allegations contained in Paragraph 44 of 19 Plaintiff's Complaint. 20 45. Defendants deny the remaining allegations contained in Paragraph 45 of 21 Plaintiff's Complaint. 22 46. Defendants admit the G2® Filter System was cleared by the United States Food 23 and Drug Administration in 2005 for permanent use pursuant to an application submitted 24 under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants further admit that the 25 G2® Filter was subsequently cleared for retrievable use in 2008. Defendants deny the 26 remaining allegations contained in Paragraph 46 of Plaintiff's Complaint, including any

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allegations contained in Footnotes 1 and 2.

1	47.	Defendants	deny	the	allegations	contained	in	Paragraph 47	of	Plaintiff's
2	Complaint.									
3	48.	Defendants	deny	the	allegations	contained	in	Paragraph 48	of	Plaintiff's
4	Complaint, a	as stated.								
5	49.	Defendants	deny	the	allegations	contained	in	Paragraph 49	of	Plaintiff's
6	Complaint.									
7	50.	Defendants	deny	the	allegations	contained	in	Paragraph 50	of	Plaintiff's
8	Complaint.									
9	51.	Defendants	deny	the	allegations	contained	in	Paragraph 51	of	Plaintiff's
10	Complaint.									
11	52.	Defendants	deny	the	allegations	contained	in	Paragraph 52	of	Plaintiff's
12	Complaint.									
13	53.	Defendants	deny	the	allegations	contained	in	Paragraph 53	of	Plaintiff's
14	Complaint.									
15	54.	Defendants	deny	the	allegations	contained	in	Paragraph 54	of	Plaintiff's
16	Complaint.									
17	55.	Defendants	deny	the	allegations	contained	in	Paragraph 55	of	Plaintiff's
18	Complaint.									
19	56.	Defendants	deny	the	allegations	contained	in	Paragraph 56	of	Plaintiff's
20	Complaint.									
21	57.	Defendants	deny	the	allegations	contained	in	Paragraph 57	of	Plaintiff's
22	Complaint.	By way of	furthe	r ans	swer, Defen	dants adm	it t	hat there are	var	ious well-
23	documented	complication	s that	may	occur as a	result of	the	fracture, perfe	orati	on, and/or
24	migration of	any inferior	vena ca	ava f	ilter. Defend	ants further	adı	mit that it is we	ell d	ocumented
25	that many ir	stances of fil	ter fra	cture	and/or migr	ation result	in	no complicatio	ns v	whatsoever
26	but, rather,	are completel	ly asyı	npto	matic. Defer	ndants furth	ner	state that there	e ar	e incidents
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20										

related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters.

- 58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's Complaint, including all sub-parts thereof. By way of further answer, Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. Defendants further state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters.
- 59. Defendants admit that there are various well-documented complications that may occur as the result of the fracture of any inferior vena cava filter. Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. By way of further response, Defendants state that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations contained in Paragraph 59 of Plaintiff's Complaint.
- 60. Defendants deny the allegations contained in Paragraph 60 of Plaintiff's Complaint.
- 61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's Complaint. By way of further response, Defendants state that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications.
- 62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's Complaint.
- 63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's Complaint.

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1	64. Defendants admit the G2® Express Filter System was cleared by the United
2	States Food and Drug Administration pursuant to an application submitted under
3	Section 510(k) of the Food, Drug and Cosmetic Act in 2008. Defendants further admit that
4	the G2® Express Filter is similar to the G2® Filter, but includes a snare on the sheath of the
5	filter to enhance retrievability. Defendants deny any remaining allegations contained in
6	Paragraph 64 of Plaintiff's Complaint.
7	65. Defendants deny the allegations contained in Paragraph 65 of Plaintiff's
8	Complaint.
9	66. Defendants incorporate by reference their responses to Paragraphs 1-65 of
10	Plaintiff's Complaint as if fully set forth herein.
11	67. The allegations contained in Paragraph 67 of Plaintiff's Complaint are
12	conclusions of law, to which no response is required. To the extent a response is required
13	Defendants deny those allegations.
14	68. Defendants deny the allegations contained in Paragraph 68 of Plaintiff's
15	Complaint.
16	69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's
17	Complaint.

- Defendants deny the allegations contained in Paragraph 70 of Plaintiff's 70. Complaint.
- The allegations contained in Paragraph 71 of Plaintiff's Complaint regarding 71. Defendants' legal duties are conclusions of law, to which no response is required. To the extent a response is required, Defendants deny those allegations.

FIRST CAUSE OF ACTION STRICT LIABILITY MANUFACTURING DEFECT

Defendants incorporate by reference their responses to Paragraphs 1-71 of 72. Plaintiff's Complaint as if fully set forth herein.

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- 1 73. Defendants lack information or knowledge sufficient to form a belief as to the 2 truth of the allegations regarding the trade name of any inferior vena cava filter implanted in 3 Plaintiff and, therefore, deny them. Defendants admit that Bard owns a facility where vena 4 cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and 5 distributes inferior vena cava filters. Defendants deny any remaining allegations contained in 6 Paragraph 73 of Plaintiff's Complaint. 7 74. Defendants deny the allegations contained in Paragraph 74 of Plaintiff's 8 Complaint. 9 75. Defendants deny the allegations contained in Paragraph 75 of Plaintiff's 10 Complaint. 11 76. Defendants deny the allegations contained in Paragraph 76 of Plaintiff's 12 Complaint. 13 **SECOND CAUSE OF ACTION** STRICT LIABILITY INFORMATION DEFECT 14 15 77. Defendants incorporate by reference their responses to Paragraphs 1-76 of 16 Plaintiff's Complaint as if fully set forth herein. 17 78. 18 19
 - Defendants lack information or knowledge sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, therefore, deny them. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and
- 21 distributes inferior vena cava filters. Defendants deny any remaining allegations contained in
 - Paragraph 78 of Plaintiff's Complaint.
 - 79. Defendants lack information or knowledge sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, therefore, deny them. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and

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1	distributes in	nferior vena c	ava filt	ters.	Defendants	deny any re	ma	ining allegation	is co	ontained in	
2	Paragraph 79	of Plaintiff's	s Comp	olain	t.						
3	80.	Defendants	admit	that	there are v	arious well	-do	cumented com	plic	ations that	
4	may occur a	s a result of t	he frac	cture	, perforation	, and/or mi	grat	ion of any infe	rior	vena cava	
5	filter. Defen	dants further	admi	t tha	t it is well	documente	ed t	hat many inst	ance	es of filter	
6	fracture and	or migration	result	in n	o complicat	ions whatso	eve	er but, rather, a	are (completely	
7	asymptomati	ic. Bard furth	er state	es tha	at there are i	ncidents re	late	d to the occurre	ence	of known	
8	complications associated with every manufacturer of inferior vena cava filters. Defendants										
9	deny any remaining allegations contained in Paragraph 80 of Plaintiff's Complaint.										
10	81.	Defendants	deny	the	allegations	contained	in	Paragraph 81	of	Plaintiff's	
11	Complaint.										
12	82.	Defendants	deny	the	allegations	contained	in	Paragraph 82	of	Plaintiff's	
13	Complaint.										
14	83.	Defendants	deny	the	allegations	contained	in	Paragraph 83	of	Plaintiff's	
15	Complaint.										
16	84.	Defendants	deny	the	allegations	contained	in	Paragraph 84	of	Plaintiff's	
17	Complaint.										
18	85.	Defendants	deny	the	allegations	contained	in	Paragraph 85	of	Plaintiff's	
19	Complaint.										
20	86.	Defendants	deny	the	allegations	contained	in	Paragraph 86	of	Plaintiff's	
21	Complaint.										
22	87.	Defendants	deny	the	allegations	contained	in	Paragraph 87	of	Plaintiff's	
23	Complaint.										
24			<u>T</u>	HIR	D CAUSE (OF ACTIO	N				
25		<u>s</u>	TRIC	T L	ABILITY I	DESIGN D	EFI	ECT			
26	88.	Defendants	incorp	orate	e by referen	nce their re	espo	onses to Parag	raph	ns 1-87 of	
27	Plaintiff's Complaint as if fully set forth herein.										

1	89.	Defendants	lack ir	ıforn	nation or kno	owledge suf	fici	ent to form a	belie	ef as to the
2	truth of the a	allegations reg	garding	g the	trade name	of any infe	rior	vena cava filto	er in	nplanted in
3	Plaintiff and	, therefore, d	eny th	em.	Defendants a	admit that l	Baro	d owns a facili	ity v	vhere vena
4	cava filters a	re manufactu	red. D	efend	dants further	admit that	BP	V designs, sells	s, m	arkets, and
5	distributes in	nferior vena c	ava fil	ters.	Defendants of	deny any re	ma	ining allegation	ns co	ontained in
6	Paragraph 89	of Plaintiff's	s Comj	olain	t.					
7	90.	Defendants	deny	the	allegations	contained	in	Paragraph 90	of	Plaintiff's
8	Complaint.									
9	91.	Defendants	deny	the	allegations	contained	in	Paragraph 91	of	Plaintiff's
10	Complaint.									
11	92.	Defendants	deny	the	allegations	contained	in	Paragraph 92	of	Plaintiff's
12	Complaint.									
13	93.	Defendants	deny	the	allegations	contained	in	Paragraph 93	of	Plaintiff's
14	Complaint.									
15	94.	Defendants	deny	the	allegations	contained	in	Paragraph 94	of	Plaintiff's
16	Complaint.									
17	95.	Defendants	deny	the	allegations	contained	in	Paragraph 95	of	Plaintiff's
18	Complaint.									
19	96.	Defendants	deny	the	allegations	contained	in	Paragraph 96	of	Plaintiff's
20	Complaint.									
21	97.	Defendants	deny	the	allegations	contained	in	Paragraph 97	of	Plaintiff's
22	Complaint.									
23			<u>F(</u>)UR'	TH CAUSE	OF ACTION	<u>ON</u>			
24				NEC	GLIGENCE	– DESIGN	<u>1</u>			
25	98.	Defendants	incorp	orate	e by referen	ice their re	espo	onses to Parag	rapl	ns 1-97 of
26	Plaintiff's Co	omplaint as if	fully	set fo	orth herein.					
27										
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99.	Defendants deny the allegations contained in Paragraph 99 of Plaintiff's									
Complaint, i	ncluding all sub-parts thereof.									
100.	Defendants deny the allegations contained in Paragraph 100 of Plaintiff's									
Complaint, is	ncluding all sub-parts thereof.									
101.	The allegations contained in Paragraph 101 of Plaintiff's Complaint regarding									
Defendants' legal duties are conclusions of law, to which no response is required. To the										
extent a resp	onse is required, Defendants deny those allegations.									
102.	Defendants deny the allegations contained in Paragraph 102 of Plaintiff's									
Complaint, i	ncluding all sub-parts thereof.									
103.	Defendants deny the allegations contained in Paragraph 103 of Plaintiff's									
Complaint.										
FIFTH CAUSE OF ACTION										
<u>NEGLIGENCE – MANUFACTURE</u>										
104.	Defendants incorporate by reference their responses to Paragraphs 1-103 of									
Plaintiff's Co	omplaint as if fully set forth herein.									
105.	The allegations contained in Paragraph 105 of Plaintiff's Complaint regarding									
Defendants'	legal duties are conclusions of law, to which no response is required. To the									
extent a resp	onse is required, Defendants deny those allegations.									
106.	Defendants deny the allegations contained in Paragraph 106 of Plaintiff's									
Complaint, is	ncluding all sub-parts thereof.									
107.	Defendants deny the allegations contained in Paragraph 107 of Plaintiff's									
Complaint.										
	SIXTH CAUSE OF ACTION									
	NEGLIGENCE – FAILURE TO RECALL/RETROFIT									
108.	Defendants incorporate by reference their responses to Paragraphs 1-107 of									
Plaintiff's Co	omplaint as if fully set forth herein.									

109.	The allegat	ions (conta	nined in Pa	aragraph 10	9 (of Plaintiff's	Com	plaint a	are
conclusions	of law, to wh	nich ne	o res	ponse is rec	juired. To 1	the	extent a respon	ise i	s require	ed,
Defendants of	leny those all	egatio	ns.							
110.	Defendants	deny	the	allegations	contained	in	Paragraph 110	of	Plaintif	f's
Complaint.										
111.	Defendants	deny	the	allegations	contained	in	Paragraph 111	of	Plaintif	f's
Complaint.										
112.	Defendants	deny	the	allegations	contained	in	Paragraph 112	of	Plaintif	f's
Complaint.										
113.	The allegati	ons co	ntaiı	ned in Parag	graph 113 o	of P	laintiff's Comp	lain	t regardi	ing
Defendants'	legal duties	are co	nclu	sions of law	, to which	no	response is re	quir	ed. To t	the
extent a response is required, Defendants deny those allegations.										
114.	Defendants	deny	the	allegations	contained	in	Paragraph 114	of	Plaintif	f's
Complaint.										
115.	Defendants	deny	the	allegations	contained	in	Paragraph 115	of	Plaintif	f's
Complaint.										
		<u>SE</u>	VEN	TH CAUS	E OF ACT	IO	N			
	1	NEGL	<u>IGE</u>	NCE – FAI	LURE TO	W	<u>ARN</u>			
116.	Defendants	incorp	orat	e by referer	nce their re	espo	onses to Paragr	aph	s 1-115	of
Plaintiff's Co	omplaint as if	fully	set fo	orth herein.						
117.	Defendants	deny	the	allegations	contained	in	Paragraph 117	of	Plaintif	f's
Complaint.										
118.	Defendants	deny	the	allegations	contained	in	Paragraph 118	of	Plaintif	f's
Complaint.										
119.	Defendants	deny	the	allegations	contained	in	Paragraph 119	of	Plaintif	f's
Complaint.										

1	120. Defendants deny the allegations contained in Paragraph 120 of Plaintiff's
2	Complaint.
3	121. The allegations contained in Paragraph 121 of Plaintiff's Complaint regarding
4	Defendants' legal duties are conclusions of law, to which no response is required. To the
5	extent a response is required, Defendants deny those allegations.
6	122. Defendants deny the allegations contained in Paragraph 122 of Plaintiff's
7	Complaint.
8	123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's
9	Complaint.
10	EIGHTH CAUSE OF ACTION
11	NEGLIGENT MISREPRESENTATION
12	124. Defendants incorporate by reference their responses to Paragraphs 1-123 or
13	Plaintiff's Complaint as if fully set forth herein.
14	125. Defendants lack information or knowledge sufficient to form a belief as to the
15	truth of the allegations regarding the trade name of any inferior vena cava filter implanted in
16	Plaintiff and, therefore, deny them. Defendants deny the remaining allegations contained in
17	Paragraph 125 of Plaintiff's Complaint.
18	126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's
19	Complaint.
20	127. The allegations contained in Paragraph 127 of Plaintiff's Complaint regarding
21	Defendants' legal duties are conclusions of law, to which no response is required. To the
22	extent a response is required, Defendants deny those allegations.
23	128. Defendants deny the allegations contained in Paragraph 128 of Plaintiff's
24	Complaint.
25	129. Defendants deny the allegations contained in Paragraph 129 of Plaintiff's
26	Complaint.
27	
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1	130. Defendants deny the allegations contained in Paragraph 130 of Plaintiff's										
2	Complaint.										
3	131. Defendants deny the allegations contained in Paragraph 131 of Plaintiff's										
4	Complaint.										
5	132. The allegations contained in Paragraph 132 of Plaintiff's Complaint regarding										
6	Defendants' legal duties are conclusions of law, to which no response is required. To the										
7	extent a response is required, Defendants deny those allegations.										
8	133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's										
9	Complaint.										
10	134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's										
11	Complaint.										
12	NINTH CAUSE OF ACTION										
13	<u>NEGLIGENCE PER SE</u>										
14	135. Defendants incorporate by reference their responses to Paragraphs 1-134 of										
15	Plaintiff's Complaint as if fully set forth herein.										
16	136. The allegations contained in Paragraph 136 of Plaintiff's Complaint are										
17	conclusions of law, to which no response is required. To the extent a response is required,										
18	Defendants deny those allegations.										
19	137. Defendants deny the allegations contained in Paragraph 137 of Plaintiff's										
20	Complaint, including all sub-parts thereof.										
21	138. The allegations contained in Paragraph 138 of Plaintiff's Complaint are not										
22	directed at Defendants and, therefore, require no response. To the extent a response is										
23	required, Defendants deny those allegations.										
24	139. The allegations contained in Paragraph 139 of Plaintiff's Complaint are										
25	conclusions of law, to which no response is required. To the extent a response is required,										
26	Defendants deny those allegations.										
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140. Defendants deny the allegations contained in Paragraph 140 of Plaintiff's Complaint. **TENTH CAUSE OF ACTION BREACH OF EXPRESS WARRANTY** Defendants incorporate by reference their responses to Paragraphs 1-140 of Plaintiff's Complaint as if fully set forth herein. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 142 of Plaintiff's Complaint and, therefore, deny those allegations. 143. The allegations contained in Paragraph 143 of Plaintiff's Complaint are conclusions of law, to which no response is required. To the extent a response is required, Defendants deny those allegations. 144. Defendants deny the allegations contained in Paragraph 144 of Plaintiff's Complaint. Defendants deny the allegations contained in Paragraph 145 of Plaintiff's 145. Complaint, including all sub-parts thereof. 146. Defendants deny the allegations contained in Paragraph 146 of Plaintiff's Complaint. ELEVENTH CAUSE OF ACTION **BREACH OF IMPLIED WARRANTY** Defendants incorporate by reference their responses to Paragraphs 1-146 of Plaintiff's Complaint as if fully set forth herein. 148. Defendants deny the allegations contained in Paragraph 148 of Plaintiff's Complaint. 149. Defendants deny the allegations contained in Paragraph 149 of Plaintiff's Complaint, including all sub-parts thereof.

1	150.	Defendants	deny	the	allegations	contained	in	Paragraph 150	of	Plaintiff's
2	Complaint.									
3			TV	VEL1	FTH CAUS	E OF ACT	IO	<u>N</u>		
4		<u>F</u>	RAUI	<u>UL</u>	ENT MISRI	EPRESEN'	TΑ	<u>TION</u>		
5	151.	Defendants	incorp	orat	e by referer	nce their re	espo	onses to Paragr	aph	s 1-150 of
6	Plaintiff's Co	omplaint as if	fully	set fo	orth herein.					
7	152.	Defendants	deny	the	allegations	contained	in	Paragraph 152	of	Plaintiff's
8	Complaint, in	ncluding all s	ub-pai	ts th	ereof.					
9	153.	Defendants	deny	the	allegations	contained	in	Paragraph 153	of	Plaintiff's
10	Complaint, a	s stated.								
11	154.	Defendants	deny	the	allegations	contained	in	Paragraph 154	of	Plaintiff's
12	Complaint.									
13	155.	Defendants	deny	the	allegations	contained	in	Paragraph 155	of	Plaintiff's
14	Complaint.									
15	156.	Defendants	deny	the	allegations	contained	in	Paragraph 156	of	Plaintiff's
16	Complaint.									
17	157.	Defendants	deny	the	allegations	contained	in	Paragraph 157	of	Plaintiff's
18	Complaint.									
19	158.	Defendants	deny	the	allegations	contained	in	Paragraph 158	of	Plaintiff's
20	Complaint.									
21	159.	Defendants	deny	the	allegations	contained	in	Paragraph 159	of	Plaintiff's
22	Complaint.									
23	160.	Defendants	deny	the	allegations	contained	in	Paragraph 160	of	Plaintiff's
24	Complaint.									
25	161.	Defendants	deny	the	allegations	contained	in	Paragraph 161	of	Plaintiff's
26	Complaint.									
27										
30	I									

1	162.	Defendants	deny	the	allegations	contained	in	Paragraph 162	of	Plaintiff's
2	Complaint.									
3	163.	Defendants	deny	the	allegations	contained	in	Paragraph 163	of	Plaintiff's
4	Complaint.									
5	164.	Defendants	deny	the	allegations	contained	in	Paragraph 164	of	Plaintiff's
6	Complaint.									
7	165.	Defendants	deny	the	allegations	contained	in	Paragraph 165	of	Plaintiff's
8	Complaint.									
9			THI	RTE	ENTH CAU	SE OF AC	TI	<u>ON</u>		
10			FR.	AUD	ULENT CO	NCEALM	EN	<u>VT</u>		
11	166.	Defendants	incorp	orat	e by referer	nce their re	espo	onses to Paragr	aphs	s 1-165 of
12	Plaintiff's Co	omplaint as if	fully	set fo	orth herein.					
13	167.	Defendants	deny	the	allegations	contained	in	Paragraph 167	of	Plaintiff's
14	Complaint.									
15	168.	Defendants	deny	the	allegations	contained	in	Paragraph 168	of	Plaintiff's
16	Complaint, i	ncluding all s	ub-pai	rts th	ereof.					
17	169.	Defendants	deny	the	allegations	contained	in	Paragraph 169	of	Plaintiff's
18	Complaint.									
19	170.	Defendants	deny	the	allegations	contained	in	Paragraph 170	of	Plaintiff's
20	Complaint.									
21	171.	Defendants	deny	the	allegations	contained	in	Paragraph 171	of	Plaintiff's
22	Complaint.									
23	172.	Defendants	deny	the	allegations	contained	in	Paragraph 172	of	Plaintiff's
24	Complaint.									
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2	VIOLATIO	ON OF APPL	ICAB	LE	STATE LA	W PROHI	BIT	TING CONSUN	<u> </u>	R FRAUD	
3		AND I	<u>UNFA</u>	IR I	DECEPTIVE	E TRADE	PR	ACTICES			
4	173.	Defendants	incorp	orat	e by referer	nce their re	espo	onses to Paragra	aphs	s 1-172 of	
5	Plaintiff's Co	omplaint as if	fully	set fo	orth herein.						
6	174.	The allegati	ons co	ontaiı	ned in Parag	raph 174 re	egai	ding Defendant	s' le	egal duties	
7	are conclusions of law, to which no response is required. To the extent a response is required,										
8	Defendants deny those allegations.										
9	175.	Defendants	deny	the	allegations	contained	in	Paragraph 175	of	Plaintiff's	
10	Complaint.										
11	176.	Defendants	deny	the	allegations	contained	in	Paragraph 176	of	Plaintiff's	
12	Complaint.										
13	177.	Defendants	deny	the	allegations	contained	in	Paragraph 177	of	Plaintiff's	
14	Complaint.										
15	178.	Defendants	deny	the	allegations	contained	in	Paragraph 178	of	Plaintiff's	
16	Complaint.										
17	179.	Defendants	deny	the	allegations	contained	in	Paragraph 179	of	Plaintiff's	
18	Complaint.										
19	180.	Defendants	deny	the	allegations	contained	in	Paragraph 180	of	Plaintiff's	
20	Complaint.										
21	181.	Defendants	deny	the	allegations	contained	in	Paragraph 181	of	Plaintiff's	
22	Complaint.										
23	182.	Defendants	deny	the	allegations	contained	in	Paragraph 182	of	Plaintiff's	
24	Complaint.										
25	183.	Defendants	deny	the	allegations	contained	in	Paragraph 183	of	Plaintiff's	
26	Complaint.										
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1	184.	Defendants	deny	the	allegations	contained	in	Paragraph 184	of	Plaintiff's
2	Complaint.									
3	185.	Defendants	deny	the	allegations	contained	in	Paragraph 185	of	Plaintiff's
4	Complaint.									
5	186.	Defendants	deny	the	allegations	contained	in	Paragraph 186	of	Plaintiff's
6	Complaint.									
7	187.	Defendants	deny	the	allegations	contained	in	Paragraph 187	of	Plaintiff's
8	Complaint.									
9	188.	Defendants	deny	the	allegations	contained	in	Paragraph 188	of	Plaintiff's
10	Complaint.									
11	189.	Defendants	deny	the	allegations	contained	in	Paragraph 189	of	Plaintiff's
12	Complaint.									
13	190.	Defendants	deny	the	allegations	contained	in	Paragraph 190	of	Plaintiff's
14	Complaint.									
15	191.	Defendants	deny	the	allegations	contained	in	Paragraph 191	of	Plaintiff's
16	Complaint.									
17	192.	Defendants	deny	the	allegations	contained	in	Paragraph 192	of	Plaintiff's
18	Complaint.									
19	193.	Defendants	deny	the	allegations	contained	in	Paragraph 193	of	Plaintiff's
20	Complaint.									
21	194.	Defendants	deny	the	allegations	contained	in	Paragraph 194	of	Plaintiff's
22	Complaint.									
23	195.	Defendants	deny	the	allegations	contained	in	Paragraph 195	of	Plaintiff's
24	Complaint.									
25	196.	Defendants	deny	the	allegations	contained	in	Paragraph 196	of	Plaintiff's
26	Complaint.									
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1	197.	Defendants	deny	the	allegations	contained	in	Paragraph 197	of	Plaintiff's
2	Complaint.		•		C					
3	198.	Defendants	deny	the	allegations	contained	in	Paragraph 198	of	Plaintiff's
4	Complaint.		·		C					
5	199.	Defendants	deny	the	allegations	contained	in	Paragraph 199	of	Plaintiff's
6	Complaint.									
7	200.	Defendants	deny	the	allegations	contained	in	Paragraph 200	of	Plaintiff's
8	Complaint.									
9	201.	Defendants	deny	the	allegations	contained	in	Paragraph 201	of	Plaintiff's
10	Complaint.									
11	202.	Defendants	deny	the	allegations	contained	in	Paragraph 202	of	Plaintiff's
12	Complaint.									
13	203.	Defendants	deny	the	allegations	contained	in	Paragraph 203	of	Plaintiff's
14	Complaint.									
15	204.	Defendants	deny	the	allegations	contained	in	Paragraph 204	of	Plaintiff's
16	Complaint.									
17	205.	Defendants	deny	the	allegations	contained	in	Paragraph 205	of	Plaintiff's
18	Complaint.									
19	206.	Defendants	deny	the	allegations	contained	in	Paragraph 206	of	Plaintiff's
20	Complaint.									
21	207.	Defendants	deny	the	allegations	contained	in	Paragraph 207	of	Plaintiff's
22	Complaint.									
23	208.	Defendants	deny	the	allegations	contained	in	Paragraph 208	of	Plaintiff's
24	Complaint.									
25	209.	Defendants	deny	the	allegations	contained	in	Paragraph 209	of	Plaintiff's
26	Complaint.									
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1	210.	Defendants	deny	the	allegations	contained	in	Paragraph 210	of	Plaintiff's
2	Complaint.									
3	211.	Defendants	deny	the	allegations	contained	in	Paragraph 211	of	Plaintiff's
4	Complaint.									
5	212.	Defendants	deny	the	allegations	contained	in	Paragraph 212	of	Plaintiff's
6	Complaint.									
7	213.	Defendants	deny	the	allegations	contained	in	Paragraph 213	of	Plaintiff's
8	Complaint.									
9	214.	Defendants	deny	the	allegations	contained	in	Paragraph 214	of	Plaintiff's
10	Complaint.									
11	215.	Defendants	deny	the	allegations	contained	in	Paragraph 215	of	Plaintiff's
12	Complaint.									
13	216.	Defendants	deny	the	allegations	contained	in	Paragraph 216	of	Plaintiff's
14	Complaint.									
15	217.	Defendants	deny	the	allegations	contained	in	Paragraph 217	of	Plaintiff's
16	Complaint.									
17	218.	Defendants	deny	the	allegations	contained	in	Paragraph 218	of	Plaintiff's
18	Complaint.									
19	219.	Defendants	deny	the	allegations	contained	in	Paragraph 219	of	Plaintiff's
20	Complaint.									
21	220.	Defendants	deny	the	allegations	contained	in	Paragraph 220	of	Plaintiff's
22	Complaint.									
23	221.	Defendants	deny	the	allegations	contained	in	Paragraph 221	of	Plaintiff's
24	Complaint.									
25	222.	Defendants	deny	the	allegations	contained	in	Paragraph 222	of	Plaintiff's
26	Complaint.									
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1	223.	Defendants	deny	the	allegations	contained	in	Paragraph 223	of	Plaintiff's
2	Complaint.									
3	224.	Defendants	deny	the	allegations	contained	in	Paragraph 224	of	Plaintiff's
4	Complaint.									
5	225.	Defendants	deny	the	allegations	contained	in	Paragraph 225	of	Plaintiff's
6	Complaint.									
7	226.	Defendants	deny	the	allegations	contained	in	Paragraph 226	of	Plaintiff's
8	Complaint.									
9	227.	Defendants	deny	the	allegations	contained	in	Paragraph 227	of	Plaintiff's
10	Complaint.									
11	228.	Defendants	deny	the	allegations	contained	in	Paragraph 228	of	Plaintiff's
12	Complaint.									
13	229.	Defendants	deny	the	allegations	contained	in	Paragraph 229	of	Plaintiff's
14	Complaint.									
15		<u>P</u>	UNIT	IVE	DAMAGE	S ALLEGA	AT]	<u>IONS</u>		
					a by rafarar	saa thair ra		ngag to Dorogra		1 220 of
16	230.	Defendants	incorp	orat	e by leferer	ice men re	spc	nises to raragia	aphs	5 1-229 01
16 17		Defendants omplaint as if	_			ice men re	espc	mises to raragio	aphs	5 1-229 01
	Plaintiff's Co	omplaint as if	fully	set fo	orth herein.			Paragraph 231	-	
17	Plaintiff's Co	omplaint as if	fully	set fo	orth herein.				-	
17 18	Plaintiff's Co 231. Complaint.	omplaint as if Defendants	fully s	set fo	orth herein.	contained	in		of	Plaintiff's
17 18 19	Plaintiff's Co 231. Complaint.	omplaint as if Defendants	fully s	set fo	orth herein.	contained	in	Paragraph 231	of	Plaintiff's
17 18 19 20	Plaintiff's Co 231. Complaint. 232.	omplaint as if Defendants Defendants	fully some	the	orth herein. allegations allegations	contained contained	in	Paragraph 231	of of	Plaintiff's Plaintiff's
17 18 19 20 21	Plaintiff's Co 231. Complaint. 232. Complaint.	omplaint as if Defendants Defendants	fully some	the	orth herein. allegations allegations	contained contained	in	Paragraph 231 Paragraph 232	of of	Plaintiff's Plaintiff's
17 18 19 20 21 22	Plaintiff's Co 231. Complaint. 232. Complaint. 233.	Defendants Defendants Defendants Defendants	deny deny deny	the the	orth herein. allegations allegations allegations	contained contained	in in	Paragraph 231 Paragraph 232	of of	Plaintiff's Plaintiff's Plaintiff's
17 18 19 20 21 22 23	Plaintiff's Co 231. Complaint. 232. Complaint. 233. Complaint.	Defendants Defendants Defendants Defendants	deny deny deny	the the	orth herein. allegations allegations allegations	contained contained	in in	Paragraph 231 Paragraph 232 Paragraph 233	of of	Plaintiff's Plaintiff's Plaintiff's
17 18 19 20 21 22 23 24	Plaintiff's Co 231. Complaint. 232. Complaint. 233. Complaint. 234.	Defendants Defendants Defendants Defendants	deny deny deny	the the	allegations allegations allegations allegations	contained contained contained	in in in	Paragraph 231 Paragraph 232 Paragraph 233	of of of	Plaintiff's Plaintiff's Plaintiff's
17 18 19 20 21 22 23 24 25	Plaintiff's Co 231. Complaint. 232. Complaint. 233. Complaint. 234. Complaint.	Defendants Defendants Defendants Defendants	deny deny deny	the the	allegations allegations allegations allegations	contained contained contained	in in in	Paragraph 231 Paragraph 232 Paragraph 233 Paragraph 234	of of of	Plaintiff's Plaintiff's Plaintiff's

1	236. Defendants deny the allegations contained in Paragraph 236 of Plaintiff's							
2	Complaint.							
3	237. Defendants deny the allegations contained in Paragraph 237 of Plaintiff's							
4	Complaint.							
5	238. Defendants deny the allegations contained in Paragraph 238 of Plaintiff's							
6	Complaint.							
7	239. Defendants deny the allegations contained in Paragraph 239 of Plaintiff's							
8	Complaint.							
9	240. Defendants deny the allegations contained in Paragraph 240 of Plaintiff's							
10	Complaint.							
11	PRAYER FOR RELIEF							
12	Furthermore, responding to the unnumbered Paragraph, including sub-parts, following							
13	the heading "PRAYER FOR RELIEF" and beginning "WHEREFORE," Defendants deny the							
14	allegations contained in such Paragraph and all sub-parts thereof.							
15	Defendants further deny each and every allegation not specifically admitted herein.							
16	<u>DEFENSES</u>							
17	Defendants allege as affirmative defenses the following:							
18	1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which							
19	relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.							
20	2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the							
21	negligence of a person or persons or entity for whose acts or omissions Defendants were and							
22	are in no way liable.							
23	3. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of							
24	limitations and/or statute of repose.							
25	4. If Plaintiff has been damaged, which Defendants deny, any recovery by							
26	Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or							
27	failed to mitigate her alleged damages. To the extent Plaintiff has failed to mitigate her							
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alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

- 5. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiff.
- 6. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.
- 7. The conduct of Defendants and the subject product at all times conformed to the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.
- 8. If Plaintiff has been damaged, which Defendants deny, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Defendants are not legally responsible.
- 9. There was no defect in the product at issue with the result that Plaintiff is not entitled to recover against Defendants in this cause.
- 10. If there were any defect in the products and Defendants deny that there were any defects nevertheless, there was no causal connection between any alleged defect and the product on the one hand and any damage to Plaintiff on the other with the result that Plaintiff is not entitled to recover against Defendants in this cause.
- 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to by other persons or entities that are severally liable for all or part of Plaintiff's alleged injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,

either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause Plaintiff's alleged damages.

- 12. Plaintiff's claims are barred to the extent that the injuries alleged in the Plaintiff's Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a manner not intended by Defendants and over which Defendants had no control.
- 13. Plaintiff's claims are barred to the extent that the injuries alleged in the Plaintiff's Complaint were caused by a substantial change in the product after leaving the possession, custody, and control of Defendants.
- 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or Defendants.
- 15. Plaintiff's claims for breach of implied warranty must fail because the product was not used for its ordinary purpose.
- 16. Defendants neither had nor breached any alleged duty to warn with respect to the product, with the result that Plaintiff is not entitled to recover in this cause.
- 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate warnings and instructions to learned intermediaries.
- 18. At all relevant times, herein, Plaintiff's physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of the subject product.
- 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or entities for whose conduct Defendants are not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the product and other independent causes, constitute an intervening and superseding cause of Plaintiff's alleged damages.

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- 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical
- conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
- unknown, unknowable, or not reasonably foreseeable to Defendants.
- 21. Defendants believe, and upon that ground allege, that Plaintiff was advised of the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed consent, release, waiver, or comparative fault, this conduct bars in whole or in part the damages that Plaintiff seeks to recover herein.
- 22. At all relevant times during which the device at issue was designed, developed, manufactured, and sold, the device was reasonably safe and reasonably fit for its intended use, was not defective or unreasonably dangerous, and was accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.
- 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.
- 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver, estoppel, and/or laches.
- 25. If Plaintiff suffered any damages or injuries, which is denied, Defendants state that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the doctrines of contributory and/or comparative negligence.
- 26. In the further alternative, and only in the event that it is determined that Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff, any other defendants, third-party defendants, or other persons, including any party immune

because bankruptcy renders them immune from further litigation, as well as any party, codefendant, or non-parties with whom Plaintiff has settled or may settle in the future.

- 27. Should Defendants be held liable to Plaintiff, which liability is specifically denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff from all collateral sources.
- 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of claims, and the prohibition on double recovery for the same injury.
- 29. The injuries and damages allegedly sustained by Plaintiff may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff over which Defendants had no control.
- 30. The conduct of Defendants and all activities with respect to the subject product have been and are under the supervision of the Federal Food and Drug Administration ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.
- 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies provided by the Restatements (Second and Third) of Torts and reserve the right to amend their Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.
- 32. The device at issue complied with any applicable product safety statute or administrative regulation, and therefore Plaintiff's defective design and warnings-based claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and comments thereto.
- 33. Plaintiff cannot show that any reasonable alternative design would have rendered the inferior vena cava filter as alleged in Plaintiff's Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could Defendants have known of any alternative design that may be identified by Plaintiff.

- 1 34. The device at issue was not sold in a defective condition unreasonably dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and comparable provisions of the Restatement (Third) of Torts (Products Liability).
 - 35. At all relevant times during which the device at issue was designed, developed, manufactured, and sold, the device was reasonably safe and reasonably fit for its intended use, was not defective or unreasonably dangerous, and was accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.
 - 36. Defendants specifically plead all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.
 - 37. Plaintiff's alleged damages, if any, should be apportioned among all parties at fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors Act.
 - 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.
 - 39. To the extent the claims asserted in Plaintiff's Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate Defendants' rights under the Constitution of the United States and analogous provisions of the Georgia Constitution.
 - 40. To the extent Plaintiff seeks punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.

June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

- 41. Any of Plaintiff's claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and similar provisions of the Georgia Constitution, on grounds including the following:
 - (a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
 - (b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;
 - (c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against Defendants, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
 - (d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
 - (e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate

- Case 2:15-md-02641-DGC Document 453 Filed 01/25/16 Page 34 of 36 1 the Equal Protection Clause of the Fourteenth Amendment of the United States 2 Constitution; 3 (f) the procedures pursuant to which punitive damages are awarded permit the 4 imposition of punitive damages in excess of the maximum criminal fine for the 5 same or similar conduct, which thereby infringes upon the Due Process Clause 6 of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the 7 Fourteenth Amendment of the United States Constitution; 8 the procedures pursuant to which punitive damages are awarded permit the (g) 9 imposition of excessive fines in violation of the Eighth Amendment of the 10 United States Constitution; 11 the award of punitive damages to the plaintiff in this action would constitute a (h) 12 deprivation of property without due process of law; and 13 (i) the procedures pursuant to which punitive damages are awarded permit the 14 imposition of an excessive fine and penalty. 15 42.
 - 42. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiff has failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.
 - 43. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

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1	WHEREFORE, Defendants aver that Plaintiff is not entitled to the relief demanded in
2	the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action
3	against them be dismissed and that they be awarded their costs in defending this action and
4	that they be granted such other and further relief as the Court deems just and appropriate.
5	This 25th day of January, 2016.
6	
7	s/Richard B. North, Jr. Richard B. North, Jr.
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CERTIFICATE OF SERVICE I HEREBY CERTIFY that on January 25, 2016, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record. s/Richard B. North, Jr. Richard B. North, Jr. Georgia Bar No. 545599 NELSON MULLINS RILEY & SCARBOROUGH, LLP Atlantic Station 201 17th Street, NW / Suite 1700 Atlanta, GA 30363 PH: (404) 322-6000 FX: (404) 322-6050 Richard.North@nelsonmullins.com